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EXAMINER

HENLEY III, R

ART UNIT PAPER NUMBER

1205

8

DATE MAILED: 04/14/92

LIMBACH, LIMBACH & SUTTON
JAMES C. WESEMAN
2001 FERRY BLDG.,
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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4/17/92 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice re Patent Drawing, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, Form PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

- ☒ Claims 1-27 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☐ Claims _____ have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 1-27 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
- ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

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Claims 1-27 are presented for examination.

Applicant's amendment filed January 17, 1992 has been received and entered into the application.

Accordingly, claims 1, 9, 10, 14, 18 and 22 have been amended.

Claims 1 and 14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In further explanation.

(1) In claims 1 and 14, the phrase "as a primary nutritional component of said solution" is unclear as to its intended limiting effect, i.e. qualitative or quantitative.

In view of applicant's amendments and arguments, the rejection of claims 9, 10, 14, 16, 18, 21, 22 and 27 under 35 USC 112 as set forth in the last Office action at page 2 is withdrawn.

Claims 1-4, 10-12, 14, 15, 17, 23 and 24 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Kober, already of record, for the reasons of record as expressed in the last Office action at pages 3-4.

Applicants arguments have been carefully considered but fail to persuade the Examiner of error in his determination.

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Kober provides an adequate disclosure to enable the skilled artisan to make and administer a composition which has the structural and/or physical characteristics required by applicant for nutritional purposes. As such it is seen to anticipate applicant's claimed subject matter.

Applicant's requirement that the lactic acid salt serves "as a primary nutritional component" does not impart any structure and/or physical feature to the claimed composition which is not provided for by Kober.

This is also true for the limitation that the supplement is for "restoring a mammal's fluid, electrolyte and carbohydrate balance during exercise and subsequent recovery" (claim 14) since such addresses the manner in which the composition is to be employed and this claim defines a composition of matter.

The recitation of the intended use of a composition does not cause that composition, which is otherwise taught by the prior art, to undergo a metamorphosis to a new composition. See In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Respecting applicant's method of use claims for which claim 1 is representative, the method requires that the lactic acid salt composition as discussed supra is administered to a mammal for the purpose of supplying nutritional supplementation. Such a purpose and step of administration is clearly provided for by Kober as is the composition which comprises a lactic acid salt.

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Accordingly, these claims remain properly rejected.

Applicant alleges that the mineral salt concentrations present in the disclosure of Kober are far too concentrated, and the presence of lactate is far too minimal, to have the effect required by the functional language of the claims.

However, this allegation is not supported on the record by any objective evidence and it is not clear as to what part of Kober's disclosure is being compared. Also, given that applicant's specification points out that "the dosage required for therapeutic efficacy will range from about 0.1 to 50%, more usually 1 to 10% by weight "(pg. 19, lines 17-19), applicant's characterization of Kober is not persuasive.

Applicant also argues that in teaching fruit juice (which contain fructose), Kober does not highlight the beneficial effect thereof as identified by applicant, namely that fructose is metabolized in the body by the same pathway as lactate, thus enhancing the benefits of lactate nutrition.

However, this is not a requirement of the claims and even if it was, it is maintained that the mere recitation of a newly discovered function or property of a composition or its ingredients does not cause claims drawn to that composition to distinguish over a prior art composition which is otherwise taught to be old.

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Respecting applicant's position that at column 2, line 97 Kober makes reference to organic lactate which constitutes an obscure reference previously of concern to the Examiner, applicant should note that it was the phrase "organic lactic acid salt" standing alone which was criticized. The disclosure of Kober at column 2, lines 95-99 is sufficiently clear to enable the skilled artisan to make and use the disclosed invention.

Finally, it is argued that Kober fails to highlight the benefits of enhancing exercise and recovery. However, for the same reasons explained above respecting applicant's use of fructose, this point is not of the significance as urged.

Claims 1-7, 10-20 and 23-27 are rejected under 35 U.S.C. § 103 as being unpatentable over Millman in view of Kober, each of record, for the reasons of record as set forth in the previous Office action at pages 4-5.

Applicant's arguments have been given careful consideration, but fail to persuade the Examiner of error.

Applicant's argument that the references fail to recognize that lactate can comprise an important source of nutrition and other benefits as identified by applicant is noted however such does not serve to establish the non-obviousness of the claimed subject matter.

The prior art suggests doing what applicant is claiming and it has not been demonstrated that applicant's combination of ingredients produces any results that would have been unexpected to those skilled in the art. Accordingly, applicants position, which lacks adequate support, is insufficient to overcome this rejection.

Claims 1-27 remain rejected under 35 U.S.C. § 103 as being unpatentable over Adibi et al. in view of Kawajiri, each of record, for the reasons of record as set forth in the previous Office action at pages 5-7.

Applicant's arguments have been given careful consideration, but fail to persuade the Examiner of error in his determination.

It is argued by applicant that Adibi teaches a composition that is far too concentrated to be of any use to an athlete during severe exercise as it would cause dehydration and nitrogen toxicity during exercise.

However, this argument is based upon the use of a composition containing 40-50% of polypeptide and amino acids. Adibi clearly indicates at the last line of page 3 that the total protein content may be as low as 2%.

Respecting Kawajiri, applicant initially points out that lactic acid is utilized by the patentee while lactate is not. However, in addition to using lactic acid, per se, which is not patentably excluded from applicant's claims, i.e.

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"comprising...", the reference further highlights lactic acid salts, e.g. column 1, lines 58-62.

Respecting applicant's position that the Examiner has improperly combined references in determining the obviousness of the claimed invention, it is recognized that references cannot be arbitrarily combined and that there must be some reason why the skilled artisan would have been motivated to make the proposed combination of primary and secondary references, there is no requirement that such a motivation be expressly articulated.

In each of the rejection under 35 USC 103, the Examiner has expressed the reason why a skilled artisan would have been motivated to reconcile the difference between the prior art and the claimed subject matter. While applicant offers a different reason for the use of a lactic acid salt in a nutritional composition than does the prior art, the references nevertheless support that it would have been obvious to make such a composition and to employ it in the manner herein claimed.

Compare In re Lintner, 173 USPQ 80 (CCPA 1975) where it was held that the fact that appellant used sugar (as compared to applicant's lactic acid salt) for a different purpose does not alter the conclusion that its use in a prior art composition would have been prima facie obvious from the purposes disclosed in the references.

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Thus, the Examiner is maintaining that the propriety of the instant rejections remains intact.

None of the claims are allowed.

Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Henley whose telephone number is (703) 308-4652.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Frederick E. Waddell
Supervisory Patent Examiner
Group 120

Henley: ach
April 03, 1992
April 07, 1992



RAYMOND J. HENLEY III
PATENT EXAMINER
GROUP 120 - ART UNIT 125